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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,936	07/03/2001	Paul DiCarlo	BSI-479US	1985

7590

12/10/2003

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EXAMINER

LANDREM, KAMRIN R

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/10/2003

10⁴

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,936

Applicant(s)

DICARLO, PAUL

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 25-27 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 25-27 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 9, 11, 15, 25-27, 36, 38, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Balbierz et al (USPN 5,964,744).

With reference to Figure 4, Lentz discloses a prosthetic component 10 comprising a vascular graft (3:4) having proximal 14 and distal 16 ends. Hems 20 and 21 are disposed on ends 14 and 16. Lentz further discloses a stent 28 that is disposed within hems 20 and 21 of graft 10. Lentz discloses the method of implanting the prosthetic component (4:43+). Lentz discloses the claimed prosthetic however Lentz fails to disclose a cord disposed within the hems that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen. Balbierz teaches in Figure 12 cord shaped stent comprising a coated (10:46-48) polymer material that is physiologically acceptable (1:15-24) that upon hydration is capable of expanding to a predetermined shape to aid in retention. (7:46-57) Therefore, in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the polymer material as taught by Balbierz into the hems of the prosthesis

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disclosed by Lentz in order to produce a prosthesis that is capable of expanding and fixating securely against the walls of a body lumen.

Claims 6,7, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Balbierz et al.

As discussed above, Lentz as modified by Balbierz discloses the claimed device for implantation into a body lumen. Lentz as modified does not expressly disclose the flat-ribbon shape or the thickness of the cord. At the time the invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have made the cord of a thin flat shape to place into the hems of the graft prosthesis because the applicant has not disclosed that a cord that is less than thirty thousandths of an inch thick and has a flat ribbon shape provides an advantage, is used for a particular purpose, or solves a staged problem. One of ordinary skill in the art, further more, would have expected Applicants invention to perform equally well with the circular shaped device as taught by Balbierz because it is capable of being placed within the hems of the prosthesis disclosed by Lentz and expanding upon contact with bodily fluids to provide a secure attachment to the body lumen.

Claims 10, 14, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz as modified further in view of Solovay (USPN 5,769,884).

As discussed above, Lentz as modified by Balbierz discloses the claimed device for implantation into a body lumen. Lentz however does not disclose variable porosity or permeability of the device. With reference to Figures 6-6E Solovay teaches a device for placement into a body lumen that has variable pore size and permeability to allow for healthy tissue and capillary ingrowth near the ends of the stent (2:13+). Therefore in view of the

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teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have increased the porosity in the area of the hems to provide increased permeability for fluid expansion of the cord and to increase healthy tissue ingrowth thus providing additional support of the device within the lumen of the body.

Claims 12, 13, 35, 39, and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz as modified, further in view of Lauterjung (USPN 5,824,036).

As discussed above, Lentz as modified by Balbierz discloses the claimed device for implantation into a body lumen. Lentz however does not disclose a stent placed within the graft device that extends protrudes distally from the graft device. With reference to Figure 3 Lauterjung teaches a stent graft combination comprising a stent 154 contained within a graft 112 with portions 156 extending away from the end of the graft for anchoring the graft to to the inside of the lumen and thereby assist in holding the device assembly in place (4:10-15). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device disclosed by Lentz by incorporating an inner stent that extends before the end of the graft to provide further anchoring and support for the luminal device.

Response to Arguments

Applicant's arguments with respect to claims 1-15, 25-27, and 35-43 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061.

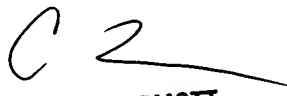
The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-308-3905.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738

KRL


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700